

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS)	
CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 23-975-RGA-SRF
)	
LIQUIDIA TECHNOLOGIES, INC.,)	
)	
Defendant.)	

OPENING BRIEF IN SUPPORT OF DEFENDANT'S MOTION TO STRIKE

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I. INTRODUCTION

Through its own discovery failures and objections, UTC has forfeited the right to challenge the prior art status of the '793 Patent based on the common ownership exception of 35 U.S.C. § 102(b)(2)(C) (“(b)(2)(C)”). Despite Liquidia’s interrogatory seeking exactly this information, UTC failed to disclose this theory during discovery. To the contrary, UTC waited until the close of fact discovery—November 13, 2024—to divulge its (b)(2)(C) defense, but obscured it by editing its *original* July 2024 response without disclosing its change. And even then, UTC did not affirmatively assert the '793 was not prior art, nor did it identify any evidence—not even Dr. Byrd’s conclusory testimony on which it now relies. Liquidia thus requests the Court strike UTC’s § 102(b)(2)(C) defense and evidence and issue an order establishing that the '793 Patent is prior art to the '327 Patent for the purposes of this action.

II. SUMMARY OF ARGUMENT

1. Rule 37(c)(1) forbids a party that “fails to provide information or identify a witness” during discovery from “us[ing] that information or witness to supply evidence on a motion, at a hearing, or at a trial” unless the failure was “substantially justified or is harmless.”

2. Liquidia timely served an interrogatory seeking the basis for any claim that any invalidity reference did not qualify as prior art, and specifically requesting identification of any relevant documents or persons with knowledge. UTC failed to provide that information.

3. By failing to identify its common ownership theory, and never identifying the evidence it relied on at trial, UTC deprived Liquidia of the opportunity to take discovery, including by deposing Dr. Byrd (or others) about the basis for his alleged knowledge of UTC’s patents, and seeking additional 30(b)(6) depositions about the assignment history of the '793 and '327 Patents. Because this failure was not substantially justified or harmless, UTC forfeited the right to present its § 102(b)(2)(C) theory or evidence.

4. The '810 Application, relied on in UTC's Responsive Post-Trial Brief, faces an additional hurdle—this Court admitted it only for the limited purpose of cross-examining UTC's expert Dr. Nathan regarding the absence of specific data from the INCREASE trial. The Court imposed this limitation based on UTC's strenuous objections against general admission of the document. Because it admitted the '810 Application only for this limited purpose, not to proving ownership of the application, “the [C]ourt, on timely request, must restrict the evidence to its proper scope” Fed. R. Civ. P. 105; *see also Endo Pharms. Inc. v. Amneal Pharms., LLC*, 224 F. Supp. 3d 368, 375 n.5 (D. Del. 2016). Thus, the Court should preclude UTC from using the '810 Application to support its untimely § 102(b)(2)(C) argument.

III. STATEMENT OF FACTS

A. UTC Failed to Disclose Its (b)(2)(C) Theory in Discovery

Liquidia served its initial invalidity contentions on June 4, 2024. D.I. 97. Those contentions included arguments that the '793 Patent is prior art that anticipated and/or rendered obvious various claims of the '327 Patent. The next day, Liquidia served its first set of interrogatories on UTC. D.I. 98. Interrogatory No. 1 required UTC to describe:

. . . any disagreement as to whether any of the cited references do not constitute prior art, and [provide] a detailed recitation of all facts . . . on which You intend to rely, the persons most knowledgeable with respect to such facts, . . . and identify each document (specifically identified by production number) that relates to such facts.

Ex. A at 7.

UTC's response, served July 5, 2024, did not describe any common ownership argument regarding the '793 Patent. Instead, it stated that Liquidia's arguments “assume[] that the '793 patent is prior art, which Liquidia has not proven. *See* 35 U.S.C. § 102(a), (b) (post-AIA).” Ex A at 11 (emphasis added). UTC did not state or imply that UTC was the common owner of the '327 and '793 Patents as of the effective filing date of the '327 Patent, and failed to identify any evidence

that might support such a claim. At most UTC simply identified Liquidia's burden.

UTC's initial disclosures also failed to disclose Dr. Byrd as a witness with knowledge relevant to (b)(2)(C). Instead, consistent with his regulatory role, Dr. Byrd is described as having knowledge only of the NDAs and "research, development, regulatory approval, and launch of TYVASO" Ex. B at 3. Four other witnesses *were* listed as having knowledge of the '327 Patent or its prosecution, but none were described as having knowledge of patent ownership. *Id.* at 3-4. For the next four months, Liquidia litigated the case in reliance on the information UTC provided. Consistent with UTC's disclosure, Liquidia deposed Dr. Byrd on October 15, 2024, about regulatory issues, not about UTC's patent portfolio.

UTC first mentioned its (b)(2)(C) theory in a "supplement" to Interrogatory No. 1. This supplement was served on November 13, 2024—the last day of fact discovery and after the depositions of Dr. Byrd and each of the witnesses UTC described as having knowledge of the '327 Patent. D.I. 199. The supplement appeared to follow the standard format of reciting Liquidia's interrogatory, followed by a heading titled "Response to Interrogatory No. 1 (6/5/2024)¹" which based on the explicit label, indicated a repetition of UTC's original response. Ex. C at 8. UTC's "original" response was followed by a new section called "First Supplemental Response to Interrogatory No. 1 (11/13/2024)[,]" which contained new disclosures largely related to Liquidia's prior sale theory. *Id.* at 41-42. UTC's "original" response, however, was materially different from the one UTC served on July 5.

The screenshots below illustrate UTC's revision relevant to this motion. The first is from the response served on July 5, 2024, which generally cited to §§ 102(a) and (b):

¹ This appears to contain a typo, and should read *July* 5, 2024, the date UTC served its original response to Interrogatory No. 1. *See* Ex. A at 56.

Allowability). And that assumes that the '793 patent is prior art, which Liquidia has not proven.
See 35 U.S.C. § 102(a), (b) (post-AIA). Likewise, in connection with UTC's motion for a

Ex. A at 11 (highlight added).

The second is from the original "Response to Interrogatory No. 1 (6/5/2024)" portion of the November 13 supplement, which deleted UTC's original citation and replaced it with a new one to (b)(2)(C), implying it was disclosed as of July 5, 2024 when the original interrogatory responses were served:

Allowability). And that assumes that the '793 patent is prior art, which Liquidia has not proven.
See 35 U.S.C. § 102(b)(2)(C) (post-AIA). Likewise, in connection with UTC's motion for a

Ex. C at 11 (highlight added).

UTC's back-dated revision, the only reference to (b)(2)(C) during discovery, still failed to disclose any actual common ownership theory, provide any factual basis for UTC's contention, and simply recited Liquidia's burden. Here again, UTC did not affirmatively represent they commonly owned both the '793 and '327 Patents as of the April 2020 effective filing date. The common ownership theory was not addressed by UTC's experts or by any UTC fact witness during their depositions.

B. UTC Plans Its Trial Strategy Around Its Undisclosed Theory

The pretrial order contains a bare reference to UTC's common ownership theory. Even there, it appears as only a single paragraph in each of UTC's issues of fact, issues of law, and statement of intended proofs. See D.I. 334, Ex. 2 at ¶859, Ex. 4 at ¶279; D.I. 335, Ex. 17 at ¶17. None of these paragraphs provided the basis for this theory, requested almost a year earlier, and none described what evidence might be used to carry UTC's burden of production. *Id.*

Nor could UTC's ultimate strategy be gleaned from the remainder of the pretrial order. No '810 Application assignment was listed on the exhibit list – and in fact, UTC has never produced an assignment for the '810 Application that is dated on or before its effective filing date of April 17, 2020. *See* 35 U.S.C. § 102(b)(2)(C) (requiring common ownership “not later than the effective filing date”). Each person described in UTC's initial disclosures as having some knowledge of the '327 Patent (Leigh Peterson, Chunqin Deng, Stephen Maebius, and Peter Smith) was included on UTC's witness list. D.I. 335, Ex. 6. At trial, however, none of these witnesses offered testimony regarding common ownership. Moreover, UTC asked a series of leading questions to Dr. Byrd, its fact witness on the NDA and FDA regulatory matters, none directed to ownership as of the effective filing date. Tr. 35:14-16; 36:19-36:24.

Two days later, the moment Liquidia rested its invalidity case, UTC filed a Rule 52(c) motion complete with a ten-page brief that, *for the first time*, alleged common ownership of both the '793 and '327 patents based on Dr. Byrd's affirmative responses as UTC's leading questions. D.I. 398, 2-3, 8. UTC knew its strategy, but chose to withhold its evidence until trial, despite being expressly asked for it during discovery.

C. UTC Prevented Admission of the '810 Application It Seeks to Now Use

Liquidia attempted to move the '810 Application (DTX375) into evidence during the cross-examination of UTC's expert Dr. Nathan. UTC objected, and the parties argued about the relevance of the application to various issues. *See* Tr. 912:20-917:20. The Court ultimately admitted the exhibit for the limited purpose of “cross-examining Dr. Nathan about it” and “whatever purposes Mr. Davies can make here,” which consisted solely of demonstrating that certain Examples were absent from the '810 Application. *See* Tr. 917:16-919:3. UTC did not ask any questions regarding the '810 Application, let alone ownership.

IV. ARGUMENT

A. Liquidia's Motion Is Timely

The Court denied UTC's original 52(c) with instructions for UTC to raise (b)(2)(c) in its post-trial brief. Tr. 1010:18-24. The Court also stated UTC's positions reflected in its 52(c) motion were locked as of its filing. *Id.*, 914:15-17. UTC's responsive brief, however, went beyond its denied 52(c) motion by reinterpreting Dr. Byrd's testimony, relying on the '810 Application, and choosing to present new evidence to the Court in the form of its November 13, 2024 response to Rog. 1 to assert, for the first time post-trial, that it had identified its (b)(2)(C) theory throughout the litigation. D.I. 431, 6-9; D.I. 432 at ¶23 & Ex. 1. Liquidia could not file a motion to strike earlier because UTC's 52(c) motion was denied, and UTC has only now renewed the issue in its response brief. Liquidia also could not have anticipated UTC's further expansion of its (b)(2)(C) argument, new evidence, and new arguments it now relies on in its post-trial responsive brief. Liquidia's motion to strike is thus timely. *See Wirtgen Am., Inc. v. Caterpillar, Inc.*, No. 17-770-JDW, 2024 LX 147457, at *8 (D. Del. Aug. 19, 2024) (granting motion to strike new evidence presented for first time in post-trial brief).

B. The Pennypack Factors Support Striking UTC's Late-Disclosed Common Ownership Theory

Liquidia specifically requested UTC's contentions and evidence regarding the prior-art status of the '793 Patent. Ex. A at 7. UTC failed to provide that information through fact discovery, expert discovery, *and trial*. Even now, the basis for UTC's claim that the '793 and '327 Patents were under common ownership as of the effective filing date of April 17, 2020 is unknown. Rule 37(c) prevents UTC from "us[ing] that information or witness to supply evidence on a motion, at a hearing, or at trial" unless the failure was substantially justified or harmless. "When determining whether a party's failure to disclose was justified or harmful, and deciding whether to strike potentially critical evidence, courts in the Third Circuit consider the *Pennypack* factors: (1)

the prejudice or surprise to the party against whom the evidence is offered; (2) the possibility of curing the prejudice; (3) the potential disruption of an orderly and efficient trial; (4) the presence of bad faith or willfulness in failing to disclose the evidence; and (5) the importance of the information withheld.” *Equil IP Holdings LLC v. Akamai Techs., Inc.*, No. 22-677-RGA, 2024 LX 154421, at *2 (D. Del. Aug. 28, 2024) (citing *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997)). Here, each factor supports exclusion.

The prejudice is manifest. UTC relies on (b)(2)(C) to avoid the invalidating nature of the ’793 Patent despite failing to disclose its common ownership theory, or any facts supporting it, during fact discovery. Had UTC disclosed the facts and witness supporting the issue in July, 2024—or at any time during fact discovery—Liquidia would have: 1) deposed Dr. Byrd on ownership of the ’793 and ’327 Patents as of the effective filing date and the basis for his knowledge; 2) noticed a 30(b)(6) deposition on ownership of the ’793 and ’327 Patents as of the effective filing date; and 3) issued further interrogatories and depositions on the precise timing of any assignments of the ’793 and ’327 Patents. *See NexStep, Inc. v. Comcast Cable Communs., LLC*, No. 19-1031-RGA, 2021 LX 221784, at *8 (D. Del. Nov. 17, 2021) (granting motion to strike late-disclosed damages theory because “[a]llowing the new theory would have meant that Comcast could not have obtained targeted discovery around the factual basis of the theory.”); *Bausch & Lomb Inc. v. SBH Holdings LLC*, No 20-1463-GBW-CJB, D.I. 250 (D. Del. Feb. 5, 2025) (granting motion to strike and noting that the late disclosure “prejudice[d the moving party], as although [disclosure dedication] is a question of law, it is one that can have factual underpinnings that would need to be explored via discovery”) (Ex. D). Depending on what this discovery uncovered, Liquidia could have elected to pursue different invalidity grounds through

the narrowing process.² See *Equil*, 2024 U.S. Dist. LX 154421, at *3-5 (striking late contentions and finding prejudice where defendant might have pursued different invalidity theories). For example, Liquidia could have replaced the '793 Patent with the '507 Patent (DTX62), which has the same specification and is § 102(a) prior art to the '327 Patent.³

UTC cannot seriously contest the unfair prejudice here, given its prior motion to strike. In moving to strike portions of Liquidia's final contentions – served more than six months before trial and with more disclosure about Liquidia's invalidity defenses than UTC has provided here – UTC complained that “[h]ad Liquidia timely disclosed the theories consistent with the Court's Scheduling Order, UTC could have asked different or additional questions at depositions—including third-party depositions of individuals deposed after October 30 who are beyond the subpoena power of the Court—and pursued different or additional discovery strategies.” D.I. 241, 2-3. Notwithstanding that any prejudice to UTC had already been cured through supplemental deposition, the Court granted UTC's motion to strike. D.I. 346. The prejudice Liquidia faces from UTC's complete failure to disclose is much greater and unfair. And unlike Liquidia's final contentions, UTC tried to bury its new (b)(2)(C) theory as if part of its “original” interrogatory response.

Pennypack factors 2 and 3 support striking. An orderly trial with full discovery on the merits of UTC's theory is no longer possible, and that failure cannot be cured short of striking UTC's common ownership theory. Numerous cases, including the Court's grant of UTC's motion

² Pursuant to the Scheduling Order, final invalidity contentions were due on October 30, 2024. D.I. 45 at ¶ 3(g)(iii). Under the Court's subsequent orders (D.I. 317-318, 346), Liquidia narrowed its invalidity defenses on May 27, 2025 and May 28, 2025 (D.I. 337, 340).

³ If the Court is not inclined to strike UTC's theory in total, Liquidia asks leave to substitute the '507 Patent for the '793 Patent. Given the identical specifications, this could be done with no more than slight citation adjustments to the parties' post-trial briefs.

to strike, have found these factors favored exclusion at much earlier stages of the case. *See, e.g., Bausch & Lomb*, No. 20-1463-GBW-CJB, D.I. 250 (finding both factors favored exclusion when theory raised for the first time in summary judgment briefing) (Ex. D); *Cirba Inc. v. VMware, Inc.*, No. 19-742-GBW, 2023 LX 186434, at *9 (D. Del. Mar. 30, 2023) (finding both factors favored exclusion where new theory was disclosed approximately 8 months before trial, but order on motion to strike did not issue until 1 month before trial); *Pharmacyclics LLC v. Fresenius Kabi USA, LLC*, No. 18-192-CFC-CJB, D.I. 465 (D. Del. Aug. 28, 2020) (finding that “the parties could not complete the significant additional work needed to fairly investigate this theory prior to trial.”) (Ex. E).

As to *Pennypack* factor 4, the record strongly indicates UTC willfully failed to disclose its common ownership theory. UTC’s original response to Interrogatory No. 1, served on July 5, 2024, did not refer to 35 U.S.C. § 102(b)(2)(C) at all, citing only “35 U.S.C. § 102(a), (b).” It also included no evidence in support of any theory disputing the prior art status of the ’793 Patent, and did not even affirmatively represent the ’793 Patent was not prior art, only that Liquidia bore the burden of proof. Ex. A at 11. The “original” response was changed, without explanation and without even identifying it as changed, in the November 13, 2024, supplemental response to explicitly cite the common ownership provision “102(b)(2)(C).”⁴ Ex. C at 11. Here again, UTC provided no evidence to support any theory of common ownership to which the newly disclosed (b)(2)(C) exception would apply. *Id.* Nothing related to the (b)(2)(C) exception is new to UTC—even assuming there was indeed common ownership as of April 17, 2020, all facts, documents,

⁴ The Court already noted, in the context of Plaintiff’s motion to strike, that it “appears to be the case” “that Plaintiff’s counsel’s behavior was beneath the civility standards expected of lawyers appearing in this Court[.]” D.I. 346, 5.

and witnesses establishing such common ownership were within its possession, custody and control. Dr. Byrd has been on UTC's initial disclosures since the beginning of this case. And UTC could have identified the '810 Application, or if in existence, written assignments dated on or before April 17, 2020 for both the '793 and '327 Patents.

If willfulness is ever to be found, this is the case. *See Cirba*, 2023 LX 186434, at *10-11 (failure to include a known theory in contentions was, in a "sense," willful). And UTC's failures here are even more egregious than those that gave rise to its motion to strike Liquidia's defenses. Liquidia sought in good faith to provide additional information regarding its invalidity theories and agreed to mitigate any prejudice to UTC even before the first expert reports were exchanged – UTC made no effort to provide any information regarding its common ownership theory until late in trial after Liquidia rested.

Lastly, as to *Pennypack* factor 5, the evidence is not particularly important to UTC, who has recited many other grounds for challenging Liquidia's obviousness arguments that far exceed the pages spent on the '793 Patent's prior art status. *Compare* D.I. 431, 6-9 (discussing (b)(2)(C)) *with id.* at 9-46 (addressing obviousness). To the extent UTC now argues that this issue is case dispositive, that is all the more reason it should have been disclosed. *See Cirba*, 2023 LX 186434, at *12-13 (finding this factor favored exclusion where undisclosed theory was "key to [plaintiff's] infringement case" but plaintiff was long aware of need to supplement). UTC's refusal to respond to a directly relevant interrogatory has prejudiced Liquidia. Its conduct was neither harmless nor substantially justified, and it must be precluded from presenting this theory or the evidence it now contends supports it. D.I. 346; *See* Fed. R. Civ. P. 37(c)(1)(C); 37(b)(2)(A)(i)-(iii).

C. UTC Is Precluded from Relying on the '810 Application as Evidence of Ownership Because It Was Not Admitted for that Purpose

Once a court limits the purpose for which evidence is offered, the fact finder is barred from

considering the evidence for any other purpose. *Endo Pharms.*, 224 F. Supp. 3d at 375 n.5 (striking attempt to use “evidence admitted for one purpose for an entirely different purpose”); Fed. R. Evid. 105. This prohibition applies with equal force in the context of a bench trial. *See, e.g., E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 656 F. Supp. 1343, 1378-79 (D. Del. 1987) (refusing to consider defendant’s argument, raised for the first time in post-trial briefing, based on a document admitted during the bench trial for a limited purpose unrelated to that argument), *rev’d and vacated in part on other grounds*, 849 F.2d 1430 (Fed. Cir. 1988).

Based on UTC’s objection, the Court admitted the ’810 Application for the sole purpose of cross-examining Dr. Nathan regarding the absence of specific examples of data from the INCREASE trial. Tr. 915:23-917:20. UTC now attempts to use the ’810 Application as evidence of supposed common ownership as of the effective filing date, an entirely different purpose than it was admitted for. Indeed, UTC’s counsel engaged in lengthy objections to the entry of this document for any purpose at all. Tr. 912:20-917:20. Moreover, there is no testimony regarding actual ownership of the ’810 Application as of its filing date. The Court was clear about the scope of admission of the ’810 Application and UTC should not be permitted to use it to address their failure to meet their burden of production on the §102(b)(2)(C) exception. *See TruePosition Inc. v. Andrew Corp.*, No. 05-747-SLR, 2008 WL 205305, at *2 (D. Del. Jan. 23, 2008) (granting plaintiff’s motion to strike from defendant’s post-trial brief all reference to and argument based on evidence that was not part of the trial record). Further, because UTC is now using the ’810 Application to prove ownership, without supporting testimony, this use is hearsay that is not subject to any exception. *See* Fed. R. Evid. 801(c); 802; 803. And because UTC failed to identify the ’810 Application as relevant evidence regarding the ownership of the ’327 Patent during discovery or before trial, UTC should be precluded from relying on the ’810 Application for that

purpose. *See* Fed. R. Civ. P. 37(c)(1)(C); 37(b)(2)(A)(ii).

V. CONCLUSION

Pursuant to Fed. R. Civ. P. 37(c)(1) and Fed. R. Evid. 801-802, Liquidia asks the Court to enter an order: (1) directing that it be taken as a fact that the '793 Patent is prior art to the '327 Patent pursuant to Rule 37(b)(2)(A)(i); (2) prohibiting UTC from introducing the testimony of Dr. Byrd and the '810 Application in support of their arguments that the '793 Patent is not prior art to the '327 Patent pursuant to Rule 37(b)(2)(A)(ii); (3) striking UTC's §102(b)(2)(C) defense pursuant to Rule 37(b)(2)(A)(iii); and/or (4) permitting substitution of the '793 Patent with the '507 Patent.

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